

INTRODUCTION TO THE IACUC

The Institute of Surgical Research (ISR) and Brooke Army Medical Center (BAMC) grant the privilege of using animals for biomedical research only to individuals committed to the highest level of care for research animals, and the highest level of ethical standards in conducting biomedical research. As Department of Defense (DoD) components that conduct animal research, we must comply with all federal laws and guidelines that apply to animal research. According to DoD Policy, an animal is defined as any live vertebrate animal which is being used for research, training, testing or experimentation purposes.

Agencies involved in Regulation/Accreditation

1) The US Department of Agriculture (USDA) was granted broad authority by Congress to regulate animal research when the Animal Welfare Act (AWA) was passed. The USDA then established the regulations and standards to enforce the AWA. The AWA mandates the establishment of an Institutional Animal Care and Use Committee (IACUC) at each institution performing animal research.

2) The Office of Laboratory Animal Welfare (OLAW) is responsible for monitoring institutional compliance with Public Health Service (PHS) policy and guidelines. OLAW relies primarily on two documents important to animal research for judging compliance.

a) The PHS Policy on Humane Care and Use of Laboratory Animals incorporates nine US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training that must be considered when institutions receive support from US Government agencies.

b) *The Guide for the Care and Use of Laboratory Animals.*

3) The Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) is a non-profit organization that accredits animal facilities. AAALAC plays a critical role in ensuring high quality animal care and use in the US, but has no regulatory authority. Institutes participate in the AAALAC accreditation program by voluntarily submitting to AAALAC site visits every three years. AAALAC uses the USDA AWA regulations and regulations as well as PHS guidelines, plus other reference documents for evaluations. If an institution meets all applicable standards, then it is awarded AAALAC accreditation, a valuable symbol of institutional commitment to quality care and use of animals. For most institutions, participation in the AAALAC accreditation program is strictly voluntary. According to DoD Policy, all DoD component facilities are required to participate in the AAALAC accreditation program.

The Institutional Animal Care and Use Committee (IACUC)

Each institution with an animal care and use program must have an IACUC. The IACUC is appointed by the Institutional Official (IO), the Chief Executive Officer of an organization. The Commander of ISR is the IO for the ISR/BAMC IACUC. The IACUC is responsible for reviewing and evaluating the institution's animal care and use program, procedures, and facilities to ensure that they are consistent with the recommendations in the National Research Council's *Guide for the Care and Use of Laboratory Animals*, the Animal Welfare Act, PHS Policy, and DoD Policy. The IACUC therefore functions as the self-regulating body for animal research on behalf of the institution and is responsible for ensuring that all federal laws, regulations and policies are followed when investigators perform animal research. The duties of the IACUC include:

- 1) Conducting semi-annual facility inspections and animal care and use program reviews.
- 2) Reviewing and approving proposed research, testing, or education activities, including significant changes to approved research.
- 3) Conducting continued review of approved research activities.
- 4) Reviewing and investigating concerns involving the care and use of animals in the research facility. The IACUC is authorized to suspend an activity involving animals that it previously approved if it determines continued protocol noncompliance or animal mistreatment.

The DoD complies with all federal guidelines and requires a minimum of five members on the IACUC. The Committee must have a Chair, be composed of at least one member not affiliated with the institution, one non-scientific member, a doctor of veterinary medicine, and at least one scientific member. The BAMC/ISR committee is currently a nine member committee (Chair, Alternate Chair/Scientific member, three scientific members, two veterinarians, one non-affiliated member, and one non-scientific member) with appropriate alternates for each position.

An effective IACUC protects both the individual investigator and the institution, while inspiring confidence in the general public that animal research is being performed in an ethical manner. Research utilizing animals is a privilege, not a right, and the IACUC must do its part to make sure that animal research is performed according to the highest standards. By assuring that animal research complies with animal welfare laws and guidelines, the IACUC ensures that animals are not subjected to unnecessary pain and distress, and protects both the investigator and the institution. The entire system is built on trust. However, a single incident of serious noncompliance with animal welfare regulation or guidelines can jeopardize the entire institution's privilege of conducting animal research.

The “Three R’s”

Three important concepts to minimize animal use and pain or distress while still achieving the critical scientific objectives that lead to advances in health and medicine have been developed. These principles are known as the “three R’s,” and the IACUC is required to consider each when reviewing proposed animal research.

1) Replacement. Replacing the use of animals with non-animal techniques, such as computer models, cell culture or tissue culture systems, or in vitro assays.

2) Reduction. Reducing the number of animals used. Examples of reduction include limiting group sizes to the minimum needed to obtain statistically significant data; performing multiple experiments simultaneously so that the same control group can be used for all experiments; sharing tissues with other investigators; designing experiments so that animals serve as their own controls; and, using newer instrumentation that improves precision and reduces the number of animals needed per data point.

3) Refinement. Refinement refers to changing experiments or procedures to reduce pain or distress in those animals that must be used. Examples include using: new anesthetics that allow rapid induction and reduced recovery times; new analgesics that provide more extended pain relief postoperatively with less frequent administrations; new bleeding and injection techniques that cause less tissue damage or distress; and, improved surgical techniques that minimize trauma and the length of anesthesia.

Training Requirements

Both PHS policy and the USDA Animal Welfare Act Regulations and Standards stipulate that research personnel using animals must be trained so that they are qualified to perform research on animals. The following specific topics are required to be part of an institution’s training program:

1) Humane methods of animal maintenance and experimentation, including:

- a) The basic needs of each species of animal;
- b) Proper handling and care for the various species of animal;
- c) Proper pre-procedural and post-procedural care of animals;
- d) Aseptic surgical methods and procedures.

2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress.

3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.

4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, committee member, or laboratory personnel shall be discriminated

against or be subject to any reprisal for reporting violations of any regulation or standards under the Act.

5) Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information on such information as: appropriate methods of animal care and use; alternatives to the use of live animals in research; and, prevention of unintended and unnecessary duplication of research involving animals.

This document serves as part of your training (topics 2 and 4). In addition, the vivarium staff provides “hands-on” training opportunities periodically and “on-the-job” training for specific tasks is provided from previously-trained laboratory personnel.

Surgery Techniques and Documentation

It is important to distinguish between survival and non-survival surgery. Survival surgery is surgery in which the animal regains consciousness after anesthesia. If an animal undergoes survival surgery, sterile technique must be used to prevent postoperative infections, no matter what vertebrate species is involved. Non-survival surgery is surgery in which the animal is euthanized while under anesthesia, and does not regain consciousness. If an animal undergoes non-survival surgery, sterile technique may not be required.

Following survival surgery, documentation of postoperative care is very important. A simple rule to follow is this – “if it isn’t written down, it didn’t happen.” The USDA requires that health care records be maintained in a manner consistent with prevailing professional veterinary practice standards. For animals larger than rodents, individual health care records are usually maintained, with records of daily observations and treatments during the postoperative care period.

What if I see a problem?

- 1) If you see that animals are in danger or in pain, take immediate steps to remove animals from the threat, and notify the animal care staff or veterinarian immediately.
- 2) If you observe misuse or mistreatment of animals, or if you see procedures that you don’t think comply with federal regulations or guidelines, report it immediately to the IACUC or Attending Veterinarian (916-1264). All reports will be treated with the strictest confidentiality and you will remain anonymous. Once an allegation of mistreatment, misuse, or noncompliance is received, the USDA Animal Welfare Regulations and Standards and PHS Policy require the IACUC to review and, if warranted, investigate the allegations. The IACUC then makes recommendations to the Institutional Official, who reviews the report and decides if additional action is needed.